

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
WESTERN DIVISION**

City of Rockford, on behalf of itself and
all others similarly situated,

Plaintiff,

v.

Mallinckrodt ARD, Inc. et al.,

Defendants.

Case No. 3:17-cv-50107

Honorable Iain D. Johnston

MEMORANDUM OPINION AND ORDER

Before the Court are three motions. The plaintiff, the City of Rockford, moves for the certification of several classes under various provisions of Federal Rule of Civil Procedure 23. Dkt. 825. The four classes comprise: (1) a class of direct purchasers seeking damages; (2) a class of indirect purchasers seeking damages; (3) a class of direct purchasers seeking injunctive relief; and (4) a class as to certain issues pertaining to Express Scripts' antitrust liability. *Id.* at Ex. 2 at 1-3.

Pending alongside the class certification motion are two *Daubert* motions. The defendant, Express Scripts,¹ challenges Rockford's expert in support of class certification, Professor William Comanor, while Rockford challenges Express Scripts' expert, Dr. Mark Israel, whose opinions are largely confined to critiques of Comanor's analysis. Dkt. 863; Dkt. 879.

¹ The defendants include Express Scripts, Inc., Express Scripts Holding Co., Accredo Health Group, Inc., CuraScript, Inc., and United BioSource LLC—for simplicity, they shall be referred to collectively as Express Scripts.

In sum, the Court finds that Comanor's damages model is unreliable, so Express Scripts' *Daubert* motion seeking the exclusion of his opinions is granted to that extent. Because the inadmissibility of Comanor's damages model is alone fatal to the certification of the direct and indirect purchaser damages classes, the remainder of Express Scripts' *Daubert* motion, as well as Rockford's *Daubert* motion challenging Israel's opinions, are denied without prejudice.

As to the injunction and issues classes, Rockford's briefing does not sufficiently develop its arguments in favor of certification, so the motion as to those classes is also denied.

I. Background

The City of Rockford brings this putative class action under the federal antitrust laws, as well as the antitrust laws of several states,² alleging that Mallinckrodt (a pharmaceutical manufacturer) and Express Scripts (a drug distributor, among other things) conspired to act anticompetitively, and thereby raised the price of one of Mallinckrodt's drugs—Acthar—to a supracompetitive level. Dkt. 178 at 2-6. Rockford alleges that it was injured when, after two of its employees' children were prescribed Acthar, it was forced to pay a supracompetitive price for it under the terms of the employees' health plan. *Id.* at 6-7. In August of 2022, the claims against Mallinckrodt were dismissed after they were discharged in Mallinckrodt's bankruptcy; only Express Scripts remains as a defendant. *See* Dkt. 651.

² In January of 2019, all of Rockford's other claims were dismissed. Dkt. 178 at 62.

Rockford has moved for the certification of four plaintiff classes.

The first, a class of direct purchasers of Acthar from Express Scripts, is defined as:

All third-party payors in the United States and its territories who purchased and paid for H.P. Acthar Gel directly from the Express Scripts Entities for their own commercial use and not for resale between August 27, 2007 through the present.

The second, a class of indirect purchasers of Acthar from Express Scripts via CVS

Caremark is defined as:

All third-party payors in states of Illinois, Michigan, Tennessee and California who purchased H.P. Acthar Gel directly from CVS-Health/Caremark for their own use and not for resale between August 27, 2007 through the present.

The third, a class seeking an injunction forbidding the allegedly anticompetitive behavior between Mallinckrodt and Express Scripts, is defined as:

All third-party payors in the United States and its territories who purchased and paid for H.P. Acthar Gel directly from the Express Scripts Entities for their own use and not for resale between August 27, 2007 through the present.

And fourth, a class seeking a declaratory judgment as to certain issues of Express Scripts' antitrust liability, is defined as:

All third-party payors in the United States and its territories who purchased and paid for H.P. Acthar Gel directly or indirectly from Defendants for their own use and not for resale between August 27, 2007 through the present (the "Class Period"). On the following issues:

- (a) Whether Defendants engaged in anticompetitive conduct;
- (b) Whether Defendants conspired and agreed to restrict output and/or to raise and fix the prices of Acthar;
- (c) Whether there is an ACTH market in which Acthar is a dominant product;
- (d) Whether Mallinckrodt had a monopoly and possessed monopoly power in the ACTH market;
- (e) Whether Defendants conspired and agreed to monopolize the market for ACTH products;
- (f) Whether Defendants had a specific intent to monopolize;

- (g) Whether Defendants had a dangerous probability of achieving monopoly power;
- (h) Whether Defendants have offered non-pretextual, pro-competitive justifications that could not have been obtained through less restrictive means, and, if so;
- (i) Whether the anticompetitive effects of Defendants' conduct outweigh their proffered pro-competitive benefits, if any;
- (o) Whether the Express Scripts Entities violated Sherman Act § 1 by their conspiracy with Mallinckrodt;
- (p) Whether the Express Scripts Entities violated Sherman Act § 2 by their conspiracy with Mallinckrodt;
- (q) Whether the Express Scripts Entities violated the state antitrust laws of Illinois, Michigan, Tennessee and/or California by their conspiracy with Mallinckrodt.

Rockford proposes to exclude the following from all of the proposed classes, even if they might otherwise fall under the class definitions:

- (a) Defendants and any entity in which Defendants have a controlling interest, their present and former parents, officers, directors, employees, legal representatives, assignees and successors;
- (b) Pharmacy Benefit Managers (PBMs), like CVS/Caremark and Optum;
- (c) All government entities except for government-funded, private employee benefit plans, like the City of Rockford; (d) the States of Alaska, Maryland, New York, Texas and Washington (who settled with Mallinckrodt and the FTC in January 2017 and released all claims);
- (e) any Medicare Advantage Organization ("MAO"), their representatives, assignors, assignees or related entities;
- (f) All persons or entities who purchased Acthar for purposes of resale or directly from either Mallinckrodt or Curascript SD;
- (g) All fully insured plans;
- (h) Any consumer beneficiary of a DPP or IPP Class member, or any consumer who paid a flat co-pay, co-insurance or cash for Acthar; and
- (i) any judicial officer who is assigned to hear any aspect of this action, and their immediate families.

Dkt. 825 Ex. 2 at 1-3.

In support of class certification, Rockford has offered the expert testimony of Professor William Comanor, a professor of economics at the University of California,

Santa Barbara. Dkt. 879 Ex. 1 at 2. He has provided both an initial report and a rebuttal to the critiques offered by Express Scripts' expert, Dr. Mark Israel, a director of the economics consultancy Compass Lexecon. Dkt. 842 Ex. A at 1.

II. Legal Standard

A. Rule 23

To be certified, any proposed class must satisfy at least five requirements. All proposed classes must first satisfy the four prerequisites set out in Rule 23(a): (1) numerosity, (2) typicality, (3) commonality, and (4) adequacy of representation. If Rule 23(a) is satisfied, a proposed class must further be among one of the three types set out in Rule 23(b). *Messner v. Northshore Univ. HealthSystem*, 669 F.3d 802, 811 (7th Cir. 2012).

In assessing whether these requirements are met, the Court does not accept the plaintiff's allegations as true but must rigorously ensure the factual sufficiency of the plaintiff's motion for class certification, resolving those factual disputes that are material to the class certification decision, even if such an inquiry trenches on the merits of the action. *See Szabo v. Bridgeport Machines, Inc.*, 249 F.3d 672, 676 (7th Cir. 2001). The proponent of the class bears the burden of showing that the elements of class certification have been proven by a preponderance of the evidence. *See Messner*, 669 F.3d at 811.

B. *Daubert* motions and class certification

"Issues arising out of the use of expert witnesses at the class certification stage have [bedeviled] the federal courts" 3 William Rubenstein et al., *Newberg*

and Rubenstein on Class Actions § 7:24 (6th ed. 2023). The Seventh Circuit’s position on this vexed issue is that district courts ought to engage in a “full *Daubert* analysis” when the reliability of expert evidence that bears on the class certification decision is challenged. *Am. Honda Motor Co., Inc. v. Allen*, 600 F.3d 813, 814 (7th Cir. 2010). Still, the Court need only rule on *Daubert* motions to the extent that they are “critical”—that is, “important to an issue decisive”—to the class certification decision. *See Messner*, 669 F.3d at 812-13.

III. Analysis

A. Damages classes

i. Predominance and damages under Rule 23(b)(3)

Rockford’s proposed classes of direct and indirect purchasers both seek damages for their alleged antitrust injuries. Dkt. 825 at 14. They seek certification under Rule 23(b)(3), *id.*, which requires that Rockford show (1) that the questions of law or fact common to the members of the proposed class predominate over questions affecting only individual class members, and (2) that a class action is superior to other available methods of resolving the controversy. *Messner*, 669 F.3d at 811. The predominance analysis always begins with the elements of the underlying claims. *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011).

Here, the only claims that remain are brought under Sections 1 and 2 of the Sherman Act and under the antitrust laws of several states. Dkt. 178 at 62. Common to all of these claims are at least these three elements: (1) liability for

violation of the antitrust laws; (2) antitrust impact, or whether one was injured by the antitrust violations (that is, a causal link between the violation and *some* harm); and (3) damages, or the *extent* to which one was injured by the antitrust violations. *See Messner*, 669 F.3d at 815.

A crucial threshold issue is whether the presence of individualized questions of damages may be considered as part of the predominance inquiry. Rockford suggests that the Seventh Circuit’s *Messner* opinion forbids any such consideration, relying on this passage:

[P]laintiffs [] must show damages, but individual proof of this element of a claim . . . is not an obstacle to a showing of predominance. *It is well established that the presence of individualized questions regarding damages does not prevent certification under Rule 23(b)(3). Messner*, 669 F.3d at 815 (emphasis supplied).

Dkt. 864 at 11-12; Dkt. 825-1 at 14 n.42.

A string cite follows this passage in *Messner*; it comprises the following cases:

- [1] *See Wal-Mart v. Dukes*, 564 U.S. 338, 362 (2011) (deeming it “clear that individualized monetary claims belong in Rule 23(b)(3)”);
- [2] *Arreola v. Godinez*, 546 F.3d 788, 801 (7th Cir. 2008) (recognizing that “the need for individual damages determinations does not, *in and of itself*, require denial of [a] motion for certification” under Rule 23(b)(3));
- [3] *Hardy v. City Optical, Inc.*, 39 F.3d 765, 771 (7th Cir. 1994) (“There have been many antitrust class actions in which the relief sought was damages, and the fact that the damages would generally be different for each member of the class was not deemed an *insuperable* obstacle.”);
- [4] *Allapattah Servs. v. Exxon Corp.*, 333 F.3d 1248, 1261 (11th Cir. 2003) (“numerous courts have recognized that the *presence* of individualized damages issues *does not prevent* a finding that the common issues in the case predominate”);
- [5] *see also Klay v. Humana, Inc.*, 382 F.3d 1241, 1260 (11th Cir. 2004) (only in rare, extreme cases would individual issues of damages be so complex as to defeat class certification under Rule 23(b)(3)).

Messner, 669 F.3d at 815 (numbering and emphasis added).

Read in context, *Messner*'s language is not nearly as sweeping as Rockford argues. Instead, it simply affirms that the mere presence of fact-bound variation in damages between different class members is not alone sufficient to defeat the certification of a class—in other words, that uniformity of damages is not required for common questions to predominate.

For instance, *Messner* cites the Supreme Court's conclusion in *Wal-Mart* that “individualized monetary claims belong in Rule 23(b)(3).” 564 U.S. at 362. But this is just a rejection of the view that a class seeking individualized damages can be certified under Rule 23(b)(2); rather, only injunctive and declaratory relief can be sought under Rule 23(b)(2), because the unitary nature of those remedies—unlike with money damages—makes predominance and the superiority of the class action “self-evident,” and thereby renders the procedural protections of Rule 23(b)(3) superfluous with respect to them. *Id.* at 363. It thus implies that a finding of predominance depends on at least some inquiry into the question of damages when damages are sought. The rest of the cited cases likewise support reading *Messner* only to disclaim the notion that variation in damages will not *per se* defeat class certification.³

³ Even *Klay v. Humana, Inc.*, glossed to stand for the proposition that damages issues will only “rare[ly]” and in “extreme cases” prevent class certification, recognizes the possibility that a proposed method for computing damages could be so “insubstantial as to amount to no method at all” and thus prevent class certification. 382 F.3d at 1259.

Further, this understanding of *Messner* makes it consistent with the Supreme Court’s later discussion of the issue in *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013) (reversing the Third Circuit’s decision for its failure to “entertain arguments against [a] damages model that bore on the propriety of class certification”). *Comcast* found that a plaintiff class was improperly certified where a plaintiff’s expert failed to “establish[] that damages are capable of measurement on a classwide basis.” *Id.* An inquiry into whether there is in fact a method of measuring damages on a classwide basis based on common evidence here—the failure of which would demand denial of class certification—thus appears to be critical to the class certification decision, and a full *Daubert* analysis pertinent to issue is therefore warranted.

ii. Daubert

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Rule 702 gives the requirements for the admissibility of expert testimony:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- b) the testimony is based on sufficient facts or data;
- c) the testimony is the product of reliable principles and methods; and
- d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Kumho Tire Company, Ltd. v. Carmichael*, the Supreme Court extended *Daubert*'s standards for reliable scientific testimony to non-scientific testimony based on technical or other specialized knowledge. 526 U.S. 137, 141 (1999). The overarching aim of the court's "gatekeeping" function under Rule 702, *Kumho* explained, is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152. To fulfill its gatekeeping role, courts must evaluate (a) the proposed expert's qualifications, (b) the reliability of the expert's methodology, and (c) the relevance of the expert's testimony so that it assists the trier of fact. *Kirk v. Clark Equip. Co.*, 991 F.3d 865, 872 (7th Cir. 2021). The proponent of an expert's testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 782 (7th Cir. 2017).

iii. Rockford's damages model

Express Scripts challenges the reliability of Comanor's damages model because of its failure to control for any "nonconspiratorial factors" that may have affected the price of Acthar. Dkt. 879 at 11-12 (quoting *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 152 F.3d 588, 593 (7th Cir. 1998)). For this reason, among others, the model fails to be a reliable estimate of damages for the members of the proposed classes.

Comanor's model aims to estimate class damages by calculating the difference between (1) the price of Acthar that in fact obtained and (2) the price that hypothetically would have obtained but for Express Scripts' "anti-competitive practices." Dkt. 879 Ex. 1 at 57, 60. Comanor assumes that the quantities of Acthar sold, and the identities of the purchasers, would remain the same in this "but-for" world (another aspect of the model that Express Scripts takes issue with, but which is immaterial for present purposes), thereby easily allowing the class' aggregate damages to be calculated: simply sum the difference between the actual price and the but-for price with respect to each vial of Acthar sold from the beginning of the alleged conspiracy to its end. *Id.* at 57.

Comanor further describes how the actual price and the but-for price can themselves be ascertained formulaically. Take first the actual price. For any given vial, the wholesale acquisition cost (WAC) that obtained at the time of its sale is available. *Id.* at 60, 62-63. The average wholesale price (AWP)—what the putative direct purchaser class members paid the wholesaler (Express Scripts) for a vial of Acthar, and thus the price relevant to the damages calculation—can be derived from the prevailing WAC, because AWP was determined as a matter of course by simply inflating the WAC by a fixed markup (25% for the majority of the alleged conspiracy, and 20% starting in 2018). *Id.* at 59, 62. Thus, the actual price for any given vial is equal to the AWP, with certain customer-specific discounts, rebates, and co-insurance payments that can likewise be accounted for formulaically. *Id.* at 60, 63.

So far, so good. Comanor’s analysis of the but-for price, however, suffers from serious defects. He employs what has been termed the “yardstick” method of estimating but-for prices, in which the prices in a similar market, unaffected by the anticompetitive conduct present in the market at issue, are assumed to be a reasonable stand-in for the but-for prices that would have prevailed in the market at issue absent the anticompetitive conduct. Dkt. 864 Ex. 3 at 28.

Comanor explains that as a “specially distributed drug[],” it is difficult to find an appropriate comparison market for Acthar. *Id.* at 30. His solution is essentially to designate the pharmaceutical industry as a whole as the relevant comparison market, with comparison prices derived from the Producer Price Index (PPI) for “Pharmaceutical Preparation Manufacturing,” a monthly metric produced by the Bureau of Labor Statistics and published in a tabular form by the Federal Reserve Bank of St. Louis. Dkt. 879 Ex. 1 at 61; Dkt. 864 Ex. 3 at 30.

The but-for prices are “derived” in that the PPI does not measure prices but price levels; the price level for the beginning of the PPI data set published by the St. Louis Fed, in June of 1981, is normalized to be 100, and subsequent months show the growth in the price level relative to that baseline. FRED, Fed. Rsrv. Bank of St. Louis, *Producer Price Index by Industry: Pharmaceutical Preparation Manufacturing*, fred.stlouisfed.org/series/PCU325412325412 (last updated Mar. 14, 2024). Comanor assumes that, absent any anticompetitive conduct, the price of Acthar would be \$1,650 (the “original reported list price”) at the beginning of the conspiracy in 2007, and the but-for price in any subsequent month relative to that

baseline would simply track the increase in the price level as represented by the PPI. *See* Dkt. 879 Ex. 1 at 60-62.

So, as Comanor demonstrates, one could formulaically determine the but-for price for sales consummated in any given month by the following method:

- (1) take as given the original WAC of December 2007, which is \$1,650, and the PPI for December of 2007, which is 420.9;
- (2) consult the PPI for the month under consideration—say, October of 2018, where it is equal to 782.9;
- (3) find the ratio between the latter month and the baseline PPI of 420.9—here, 1.86;
- (4) multiply the original WAC of \$1,650 by that ratio—here, it produces a PPI-adjusted WAC of \$3,069;
- (5) inflate the PPI-adjusted WAC by 25% (or whatever the relevant markup happens to be) to produce the AWP; and finally
- (6) deflate the AWP by 17% (or whatever the customer-specific discount happens to be).

See Dkt. 879 Ex. 1 at 60-62.

The difference between (1) the actual price charged for a vial of Acthar (which can be formulaically calculated with reference to the WAC, as described above) and (2) the but-for price arrived at by the procedure just described (accounting for any

co-insurance payments), Comanor says, gives the relevant damages figure for any given sale. *Id.*⁴

There is nothing mechanically faulty with this procedure; the problems lie in, first, the *assumptions* that undergird it and, second, *the factors not accounted for* in arriving at the putative but-for price. As Comanor asserts in defending his model, the yardstick method is an approach to the calculation of damages that rests on “long-standing antitrust precedent.” Dkt. 864 Ex. 3 at 29. But its reliability hinges on the extent to which it can stand in for the market under consideration—here, the American market for Acthar—but for the alleged anticompetitive conduct, *ceteris paribus*.

To be sure, antitrust damages cannot be calculated with exactitude; attempting to quantify the difference “between what actually happened and what would have happened in a hypothetical free market” will always involve some degree of uncertainty; nevertheless, the figures arrived at must be the result of “just and reasonable inference.” *Fishman v. Est. of Wirtz*, 807 F.2d 520, 550 (7th Cir.

⁴ The Court assumes without deciding that Comanor’s model is sufficiently developed so as to constitute common evidence in favor of certification rather than remaining a mere proposal. Although at the class certification stage plaintiffs are not required to “drill down and estimate each individual class member’s damages,” the model must calculate aggregate damages. *Kleen Prod. LLC v. Int’l Paper Co.*, 831 F.3d 919, 929 (7th Cir. 2016); *see also Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 674 F. Supp. 3d 799, 841 (C.D. Cal. 2023) (“Plaintiffs cite no authority suggesting that they may provide merely a *proposal* for a model calculating damages. The Court cannot conduct a rigorous analysis of a plan written, so to speak, on a paper napkin. . . . In other words, Plaintiffs are obligated to show that their damages *are* measurable, not that they *could be*.”). Comanor provides illustrative calculations but does not carry out the analysis fully to produce an aggregate damages figure. If this were to be considered merely a proposal for a damages model, it would be yet another reason that his opinion should be given no weight on the class certification decision.

1986) (cleaned up). Without any effort to ensure that all else is in fact equal (as far as is possible) in estimating damages from his chosen counterfactual yardstick, Comanor's model is necessarily unreliable.

Take first the selection of the pharmaceutical market as a whole as the relevant yardstick, which is fundamentally unreasoned. In his initial report, virtually the only discussion of the propriety of selecting the PPI (unadjusted by any other consideration) as the yardstick by which but-for prices may be estimated is the conclusory assertion that it is appropriate because it reflects "typical pharmaceutical industry market conditions." Dkt. 879 Ex. 1 at 57. His rebuttal report elaborates slightly but is still basically conclusory. He explains that the fundamental determinant of the "prices charged for branded pharmaceuticals, on average" are the "therapeutic benefits conveyed. No other factor is nearly as important." Dkt. 864 Ex. 3 at 29. Because Acthar is an old drug with "questionable indications," therefore, he expects it would have "command[ed] a much lower price, probably no more than average" but for the anticompetitive conduct. *Id.* at 29-30.

The report's reasoning to arrive at this opinion, however, is unsound. In short, the only support for the selection of the PPI is Comanor's *ipse dixit*. See *Kumho*, 526 U.S. at 157.

First, though he attempts to support the proposition that pharmaceuticals are generally priced in accordance with their therapeutic benefits by citing a peer-reviewed study he co-authored, Dkt. 864 Ex. 3 at 29 n.59, the study and its conclusions do not fit comfortably with the facts of this case.

As the title of the study—*Strategic Pricing of New Pharmaceuticals*—indicates, it examines “empirical evidence on the leading factors affecting the prices of new pharmaceuticals, both at introduction and at 4, 6, and 8 years.” Z. John Lu & William S. Comanor, *Strategic Pricing of New Pharmaceuticals*, 80 Rev. Econ. & Stat., 1, 108, 108 (1998). The study operationalizes the concept of “therapeutic benefit” by including dummy variables that indicate a new drug’s FDA rating and whether it treats an acute illness. *See id.* at 111. Acute illnesses are defined as those that generally last no more than three months. *Id.* The FDA ratings comprise three categories—A, B, and C—assigned according to a new drug’s “therapeutic gain,” assessed on the basis of its greater efficacy, safety, or convenience in administration as compared to drugs then available on the market. *Id.*

There is clearly a disjunction between (1) the study’s operationalization of “therapeutic benefit” using the FDA ratings, which are assigned according to a drug’s advantages relative to other drugs *when it is introduced*, and Comanor’s assertion that therapeutic benefit thus defined determines drug prices; and (2) its applicability to Acthar, a drug introduced more than 50 years before the start of the alleged conspiracy—a time horizon well outside of the study’s scope, which only examined drugs up to eight years from their introduction, when the FDA rating at introduction is much more likely to be probative of its continuing therapeutic benefit. It is questionable that the study establishes, with universal applicability, that drug prices are determined by their therapeutic benefit. Although it might well be true beyond the scope of the study, Comanor does not make any argument as to

why, notwithstanding the differences, the conclusion still holds here. Without any reasoning to establish a link between price and therapeutic benefit as relevant to Acthar, the damages model is unreliable. The “how” and “why” of an expert opinion are necessary to establish reliability. *See Pursley v. City of Rockford*, No. 3:18-cv-50040, 2024 U.S. Dist. LEXIS 42105, at *15-16 (N.D. Ill. Mar. 11, 2024).

Secondly, even if the study did show that drugs’ therapeutic benefits largely determine their prices in competitive markets, Comanor makes no effort to reliably apply that proposition to the facts at hand. In the first place, he simply asserts, without any evidence, that Acthar is an “average” drug with respect to its therapeutic benefits, and therefore that the PPI, which measures the average growth in drug prices, is an appropriate yardstick. But he does not rely on the FDA ratings used in his paper to analyze therapeutic benefit; they are not discussed anywhere in his expert report. There is in fact no analysis, quantitative or qualitative, of what it means for a drug to be “average” in terms of its therapeutic benefits: by the number of indications it is used to treat, by its efficacy in treating one or more of those indications, by any potential discounting of its therapeutic benefits with reference to its side effects, and so on. There is certainly no application of any such analytical framework to Acthar, nor to the drugs which are measured as part of the PPI; and if there is no means of comparing the therapeutic effectiveness of the drugs whose prices are measured as part of the PPI to that of Acthar, there is no way of knowing whether the PPI is a reliable proxy for the growth in Acthar’s but-for prices.

Finally, even if it were true, on the whole and in general, that therapeutic benefits determine drug prices, Comanor makes no effort to control for any other factors that might have affected Acthar's price. *See generally* Reference Manual on Scientific Evidence, *Reference Guide on Multiple Regression*, 303 (3d ed. 2011). As Express Scripts argues, "[a]ny nonconspiratorial factors likely to have made the prices charged [for Acthar] higher than the prices charged [in the yardstick market] had to be taken into account in order to make a responsible estimate of the prices that [class members] would have paid had it not been for the conspiracy." *See Blue Cross*, 152 F.3d at 593. "Statistical studies that fail to correct for salient factors, not attributable to the defendant's misconduct, that may have caused the harm of which the plaintiff is complaining do not provide a rational basis for a judgment." *Id.*

Comanor's report implicitly concedes that other factors remain relevant to the determination of drug prices in saying that, compared to therapeutic effectiveness, "[n]o other factor is *nearly* as important." Dkt. 864 Ex. 3 at 30 (emphasis added). The most obvious such factor is market share, which "might [have] confer[red] enough market power" to allow Acthar to command "a price somewhat above the average." *See Blue Cross*, 152 F.3d at 593. Indeed, Comanor has previously recognized that price is affected by market structure and the presence of competitors, as it is accounted for in the *Strategic Pricing of New Pharmaceuticals* study: To assess the rate of change in drug prices over time, that paper specifies a regression that includes the variable "[n]atural logarithm of the

number of existing brand name substitutes,” which was found to be statistically significant with a negative coefficient.⁵ Lu & Comanor, *supra*, at 116.

His failure to include any correction for market power in assessing Acthar’s but-for price is therefore inexplicable, in light of Acthar’s conceded monopoly in the market for ACTH drugs. *See, e.g.*, Dkt. 825 at 2. His only defense of this omission is that buyers’ willingness to pay would be “much lower” in a hypothetical free market, but makes no attempt to quantify this effect. Dkt. 864 Ex. 3 at 29.

Further, there is no analysis of the market structures for the drugs that compose the PPI. If—as is clear from the cases, and from Comanor’s own work—market structure is an important determinant of price changes, it is crucial that there be evidence that the market structures for the drugs that compose the PPI are similar, or if not, that market structure be controlled for, by a regression or otherwise. Without any such evidence, the fundamental assumption underpinning the use of the PPI in the damages model—that there is at least a rough similarity between the two markets under consideration—is undermined, and the damages model is unreliable.

Neither is there any consideration of *how* the determinants of price might have changed over the course of the conspiracy period. Implicit in the use of an unadjusted PPI is the assumption that any factors relevant to price always varied

⁵ “The impact of competition from branded products is indicated by the coefficient of LNUM(t), which measures the number of direct substitutes after four, six, and eight years. These coefficients are negative and highly significant in all cases. More numerous rivals have the expected effect of slowing price increases.” Lu & Comanor, *supra*, at 116. The implicit inverse—that fewer rivals, or none, will lead to steeper price increases—is particularly important here.

systematically between Acthar and the comparison market. If they varied *unsystematically*, the PPI might at any given time overstate or understate the amount of damages; and if they are not assessed at all—as is true here—could do so with unknown magnitude.

In response to Dr. Israel's critique of his failure to "control for the many events that affected Acthar's price," Comanor simply asserts without demonstrating that "to the extent" any such factors were relevant, his use of the PPI as a yardstick "more than compensates" for anything that may have caused Acthar's price to grow more rapidly. Dkt. 864 Ex. 3 at 31. Again, however, this is merely *ipse dixit* rather than a reasoned conclusion.

"In my judgment," Comanor says, the PPI "overstates the pattern of Acthar prices that one would reasonably expect to find in a hypothetical free market." *Id.* at 30. To purportedly prove this, he shows that while Acthar's prices grew by a multiple of 1.78 over the conspiracy period, the PPI grew by a multiple of 2.02; therefore, he says, his estimate of but-for prices is "conservative." *Id.* at 30-31. But this proves nothing, merely assuming what is at issue: that the PPI is an appropriate yardstick. Comanor provides no reasoned assurance that it is in fact an appropriate point of comparison, and does not attempt to analyze the magnitude of any of the factors that might have varied between the two, such that we could be confident that they would not have bridged, and more, the gap between the PPI's growth and that of the price of Acthar. This makes his damages model unreliable.

Rockford argues that Comanor was not required to “parse and compartmentalize the evidence and find economic significance as to each piece,” but could instead look to the totality of the allegedly anticompetitive acts without attempting to “attribute a fixed amount of damages to any one act.” Dkt. 907 at 15 (citing *In re Suboxone*, 421 F. Supp. 3d 12, 37 (E.D. Pa. 2019)). But the problem with Comanor’s model is not his failure to decompose price increases attributable to the anticompetitive conduct as a whole into each anticompetitive act, but rather about distinguishing the effect of the unlawful conduct taken as a whole against any other factors that may have affected the price.

* * *

The class certification decision would be unaffected if, as Rockford argued, Express Scripts’ *Daubert* motion were not considered because it was not timely. Dkt. 907 at 1-3. Initially, the Court would have addressed the issue *sua sponte* as it believes it is required to protect the integrity of the court system. *See Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 704 (7th Cir. 2009); *Sommerfield v. City of Chicago*, 254 F.R.D. 317, 318-19 (N.D. Ill. 2018) (Cole, J.). Further, the flaws in Comanor’s damages model are evident on the face of his report; whether the model is excluded for unreliability on the defendants’ *Daubert* challenge, or considered but only accorded the weight to which it is entitled in the ultimate class certification decision, Rockford cannot establish by a preponderance of the evidence that common questions will predominate with respect to the classes seeking damages. *See Comcast*, 569 U.S. at 34 (“And it is clear that, under the proper standard for

evaluating certification, respondents' model falls far short of establishing that damages are capable of measurement on a classwide basis. Without presenting another methodology, respondents cannot show Rule 23(b)(3) predominance: Questions of individual damage calculations will *inevitably* overwhelm questions common to the class.” (emphasis added)); *see also In re Rail Freight Fuel Surcharge Antitrust Litig.*, 292 F. Supp. 3d 14, 42 (D.D.C. 2017) (“Previously, the Court certified the class under Rule 23 because plaintiffs had shown that [their expert’s] theory that injury-in-fact was capable of common proof was ‘plausible’ and that his regression models were ‘workable.’ After *Comcast*, this is no longer enough. Rather, under Rule 23(b)(3), the Court must undertake a rigorous analysis and determine whether there is a ‘reliable means’ of proving . . . damages through common evidence.” (citations omitted)).

Perhaps, had the appropriate analyses been done, Comanor’s conclusions would have been vindicated, and the damages model he proposes might have been shown to be a reasonable method by which to estimate the extent of the harm to the putative class members. But his report, devoid of any reasoning on key questions, does not allow for responsible conclusions to be drawn either way. Experts must show their work if their opinions are to be credited.

Comanor’s treatment of the damages model in his expert report simply does not exhibit the same “level of intellectual rigor that characterizes the practice of an expert in the relevant field,” especially as compared to his published works. *Kumho*, 526 U.S. at 152. Marred as it is by “yawning methodological gap[s],” *Moehrl v. Nat’l*

Ass'n of Realtors, No. 19-CV-01610, 2023 WL 2683199, at *6 (N.D. Ill. Mar. 29, 2023), his opinion concerning the method by which classwide damages may be calculated is therefore excluded as unreliable.

iv. Certification of the damages classes

When each class member can rely on common evidence strong enough to sustain a reasonable jury finding on the merits of a common question, a district court “may conclude that the plaintiffs have carried their burden of satisfying the Rule 23(b)(3) requirements as to that common question of law or fact.” *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 667 (9th Cir. 2022).

Rockford’s only evidence common to the class establishing that damages were capable of measurement on a classwide basis was Comanor’s damages model. With that model having been excluded as unreliable, the Court concludes that questions of individual damage calculations will “inevitably overwhelm questions common to the class.” *Comcast*, 569 U.S. at 34. The Court is cognizant that “predominance requires a qualitative assessment []; it is not bean counting,” *Butler v. Sears, Roebuck & Co.*, 727 F.3d 796, 801 (7th Cir. 2013), but plaintiffs will now have to bring their own, individual evidence as to damages—perhaps each even arguing the propriety of their own regression specification—which would make class treatment impossibly unwieldy.

Assessed qualitatively or quantitatively, the inevitability of countless individual trials on damages using individual evidence would see the individual

questions predominant. This is so even in light of the likely common questions of liability. In this case, as in others where it is essential, “[n]o damages model, no predominance, no class certification.” *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619, 626 (D.C. Cir. 2019). Rockford’s motion for certification of these damages classes is therefore denied.

B. Injunction class

Rockford further moves for certification of an injunction class under Rule 23(b)(2).⁶ Its briefing of this issue, however, completely fails to address the appropriateness of equitable relief to remedy the class’s harm. Without an assurance that such relief is “appropriate,” Fed. R. Civ. P. 23(b)(2), under the test elaborated in *eBay*, class certification is “necessarily improper.” *See Kartman v. State Farm Mut. Auto. Ins. Co.*, 634 F.3d 883, 892 (7th Cir. 2011). The motion for certification of this injunction class is therefore denied.

C. Issues class

As to the proposed issues class, Rockford’s scanty briefing fails to properly address the propriety of certifying the particular issues proposed under Rule 23(b)(3). Although the common questions of liability that tend to attend antitrust conspiracy claims are discussed at a high level of generality, the common evidence that would be used to address each particular question proposed for certification is

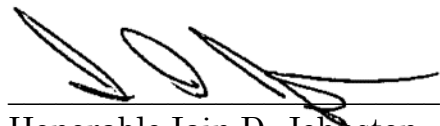
⁶ As far as the Court can discern; the briefing cites Rule 23(b)(2) in the headings of the relevant sections, but the language appears to be from Rule 23(b)(1). *See* Dkt. 825 at 13, Dkt. 864 at 10-11. If certification is sought under Rule 23(b)(1), the argument is not sufficiently developed with citations to proper authority, so any such argument is forfeited. *See, e.g., Kyles v. J.K. Guardian Sec. Servs.*, 236 F.R.D. 400, 402 (N.D. Ill. 2006).

not addressed at all. Dkt. 825 at 14-15; Dkt. 864 at 14. Rockford has thus failed to meet its burden, and the motion for certification as to the issues class is denied.

IV. Conclusion

For the foregoing reasons, Rockford's motion for class certification is denied. Express Scripts' *Daubert* motion is granted as to Comanor's opinion concerning the calculation of damages for the class. The remainder of Express Scripts' *Daubert* motion, as well as Rockford's *Daubert* motion challenging Israel's opinions, are denied without prejudice as unnecessary to the class certification decision. To the extent that the opinions addressed continue to be relevant, the *Daubert* challenges may be renewed.

Date: March 29, 2024



Honorable Iain D. Johnston
United States District Judge